DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 02/06/2004, and subsequent restriction election received on 05/09/2008.

2. Claims 1-12 have been withdrawn from consideration.

3. Claims 13-24 are currently pending and have been examined.

Information Disclosure Statement

4. The Information Disclosure Statement filed on 05/20/2004 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 22 recites the limitation "the step of generating an electrical signal." There is insufficient antecedent basis for this limitation in the claim. For the purpose of examination, the examiner will assume that claim 22 depends from claim 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 13, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodson et al. (US 6,117,142 A) in view of Lulo (US 6544225 B1).

Claim 13:

Goodson as shown discloses the following limitations:

(a) providing an elongate, flexible, hollow deployment tube having an open proximal end, a distal section terminating in an open distal end, and a lumen defined between the proximal and distal ends (see at least Fig. 1 and 6 as well as associated text)*;*

(d) introducing the endovascular device intravascularly to the target vascular site while it is attached to the deployment tube (see at least col. 2, ln 60-64)*; and*

(e) injecting a liquid into the proximal end of the lumen at a pressure of at least about 30 kg/cm^2 to separate the endovascular device from the deployment tube in response to the liquid pressure applied to the coupling element through the open distal end of the deployment tube (see at least col. 4, ln 30-53; Fig. 2-5, item# 122).

Goodson does not specifically disclose the following limitation, but Lulo as shown does:

(b) providing a filamentous endovascular device having a proximal end and a coupling element attached to the proximal end, the coupling element being releasably attached to the deployment tube adjacent the open distal end thereof, the coupling element being formed with a purge passage (see at least Fig. 2-5; item # 122; col. 2, ln 14-23 and 46-55; col. 3, ln 1-6 and 42-52)

(c) purging air from the lumen by introducing a purging liquid through the lumen with a pressure sufficient to displace air from the lumen through the purge passage but not sufficient to separate the endovascular device from the deployment tube (see at least col. 2, ln 14-23; col. 3, ln 53-60; col. 4, ln 47).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular device of Goodson to include a purge hole as shown by Lulo, because it would prevent the causation of an air embolism.

Claim 15:

Goodson discloses the limitation as shown above. Goodson however, does not specifically disclose the following limitation, but Lulo as shown does:

- *the purge passage is dimensioned so as to provide a substantial restriction to the flow therethrough of a liquid having a viscosity greater than or equal to a predetermined viscosity, and wherein the injecting step comprises the step of injecting a liquid having a viscosity greater than the predetermined viscosity through the lumen* (see at least Lulo col. 4, ln 6-24 and Goodson col. 3, ln 1-15).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular device of Goodson to include a purge passage as shown by Lulo, because "fluids with a viscosity of greater than about 1x10^-8 lb.s/in^2 will have a restricted outflow so that sufficient fluid pressure can be built up in the distal section of the catheter to release the coil during coil deployment" (see at least col. 4, ln 12-16).

Claim 16:

Goodson discloses the limitation as shown above. Goodson however, does not specifically disclose the following limitation, but Lulo as shown does:

- *the predetermined viscosity is approximately 1 cP, and wherein the relatively high viscosity liquid is a contrast agent having a viscosity of at least about 2 cP* (see at least col. 4, ln 6-24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular device of Goodson to include a purge passage as shown by Lulo, because "fluids with a viscosity of greater than about 1x10^-8 lb.s/in^2 will have a restricted outflow so that sufficient fluid pressure can be built up in the distal section of the catheter to release the coil during coil deployment" (see at least col. 4, ln 12-16).

Claims 17 and 19:

The combination of Goodson/Lulo discloses the limitation as shown above. In addition, Goodson discloses the limitations as shown below:

- *the coupling element is releasably held by a retention sleeve fixed to the distal section of the deployment tube* (see at least col. 3, ln 1-15; Fig. 2-5, item# 122).

- *the injected liquid in the injecting step applies pressure directly to the coupling element* (see at least col. 3, ln 1-15; Fig. 2-5, item# 122).

Claim 18

The combination of Goodson/Lulo discloses the limitation as shown above. In addition, Goodson discloses the limitations as shown below:

- *the retention sleeve is not substantially expanded in the radial direction during the injection step.*
  (see at least Fig. 3 & 8 item # 116; col. 4, ln 32-52)

Claim 20:

Goodson discloses the limitation as shown above. Goodson however, does not specifically disclose the following limitation, but Lulo as shown does:

- *coupling element has an exterior surface, and wherein the purge passage is formed in the exterior surface of the coupling element* (see at least col. 4, ln 6-24; Fig. 2-5, item# 130).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular device of Goodson to include a purge passage as shown by Lulo, because it would prevent the causation of an air embolism.

Claim 21

The combination of Goodson/Lulo discloses the limitation as shown above. In addition Lulo discloses "a small circular aperture 130 is located just proximal to the seal plug (see at least Fig. 2-5, item# 130)," but does not explicitly disclose that the purge passage is helical.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular device of Goodson to include a helical purge passage as shown by Lulo, since it has been held that the provision of adjustability, where needed, involves only routine skill in the art, thus the shape of the purge passage would be adjusted to the particular location in the vasculature to meet the needs and goals of the procedure. *In re Stevens,* 101 USPQ 284 (CCPA 1954)

8. Claims 14 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodson et al. (US 6,117,142 A) in view of Lulo (US 6544225 B1) further in view of Pahno et al. (US 5,269,030), Pahno herein after.

Claim 14:

The combination of Goodson/Lulo discloses the limitation as shown above. Goodson/Lulo do not explicitly disclose the following, but Pahno does:

(f) generating an electrical signal in response to the separation of the endovascular device from the deployment tube (see at least col. 34, ln 39-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular devices of Goodson/Lulo to include an electrical circuit, which would alert the operator and "provide a visual indication upon the release of the embolic coil from the deployment system" (Goodson col. 3, ln 19-24).

Claim 22:

The combination of Goodson/Lulo discloses the limitation as shown above. In addition, Goodson discloses the limitations as shown below:

- *detecting a drop in pressure in the deployment tube when the endovascular device separates from the deployment tube* (see at least Goodson col. 3, ln 19-24 and col. 6, ln 15-20)*; and*

Goodson/Lulo do not explicitly disclose the following, but Pahno does:

- *generating the signal in response to the detected drop in pressure* (see at least col. 34, ln 39-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular devices of Goodson/Lulo to include an electrical circuit, which would alert the operator and "provide a visual indication upon the release of the embolic coil from the deployment system" (Goodson col. 3, ln 19-24).

Claims 23-24:

The combination of Goodson/Lulo discloses the limitation as shown above. Goodson/Lulo do not explicitly disclose the following, but Pahno does:

- *generating the signal in response to a change in an electrical parameter in the circuit* (see at least col. 34, ln 39-61).
- *The electrical parameter is selected from the group consisting of resistance and current* (see at least col. 34, ln 5-20).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the intravascular devices of Goodson/Lulo to include an electrical circuit, which would alert the operator and "provide a visual indication upon the release of the embolic coil from the deployment system" (Goodson col. 3, ln 19-24).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHADI ALIKHANI whose telephone number is (571)270-5305. The examiner can normally be reached on Monday - Thursday 10AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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06/5/2008
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